

## **REMARKS**

### **1. Introduction**

The Office Action dated October 3, 2008, has been received and the cited references have been considered. Claims 1-12 and 29-34 have been examined and claims 13-28 have been withdrawn. Reconsideration of the outstanding rejection and allowance of the application are respectfully requested based on the following remarks.

### **2. The Obviousness Rejections of Claims 1-12 and 29-34**

On page 3 of the Office Action, claims 1-3, 5, and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,037,602 to Dabiri et al. ("Dabiri") in view of U.S. Patent No. 6,445,146 to Bergstrom et al. ("Bergstrom"). On page 4 of the Office Action, claim 4 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Dabiri in view of Bergstrom and in further view of Applicant's own disclosure. On page 5 of the Office Action, claim 7 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Dabiri in view of Bergstrom and in further view of U.S. Patent No. 6,392,246 to Wiberg et al. ("Wiberg"). On page 6 of the Office Action, claim 8 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Dabiri in view of Bergstrom and in further view of U.S. Patent No. 6,437,344 to Strawson ("Strawson"). On pages 6 and 7 of the Office Action, claims 6 and 9-11 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Dabiri in view of Bergstrom and in further view of U.S. Patent No. 4,428,908 to Ashley et al. ("Ashley"), U.S. Patent No. 5,927,351 to Zhu et al. ("Zhu"), and U.S. Patent No. 3,411,002 to Armel ("Armel"). On page 8 of the Office Action, claim 12 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Dabiri in view of Bergstrom and in further view of Wiberg and Zhu. On page 9 of the Office Action, claims 30-34

were rejected under 35 U.S.C. § 103(a) as being unpatentable over Dabiri in view of Bergstrom and in further view of Ashley, Zhu and Armel. These rejections are respectfully traversed.

Under 35 U.S.C. § 103, the U.S. Patent and Trademark Office bears the burden of establishing a prima facie case of obviousness. In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988). There are four separate factual inquiries to consider in making an obviousness determination: (1) the scope and content of the prior art; (2) the level of ordinary skill in the field of the invention; (3) the differences between the claimed invention and the prior art; and (4) the existence of any objective evidence, or “secondary considerations,” of non-obviousness. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966); see also KSR Int’l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007). An “expansive and flexible approach” should be applied when determining obviousness based on a combination of prior art references. KSR, 127 S. Ct. at 1739. However, a claimed invention combining multiple known elements is not rendered obvious simply because each element was known independently in the prior art. Id. at 1741. Rather, there must still be some “reason that would have prompted” a person of ordinary skill in the art to combine the elements in the specific way that he or she did. Id.; In re Icon Health & Fitness, Inc., 496 F.3d 1374, 1380 (Fed. Cir. 2007).

Regarding claim 1, the Office Action asserts that Dabiri discloses a transportable radioisotope production facility, particularly a radio frequency quadrupole (RFQ) linear accelerator that produces radioisotopes having application to Positron Emission Tomography (PET). The Office Action admits, and Applicant agrees, that Dabiri fails to disclose, or even suggest, a cyclotron. The Office Action asserts that Bergstrom teaches a compact cyclotron suitable for installation in a PET isotope production facility with limited space. The Office

Action concludes, therefore, that a person of ordinary skill in the art would modify the teaching of Dabiri with the cyclotron of Bergstrom. Applicant respectfully disagrees. Applicant submits that the Office Action fails to establish prima facie case of obviousness. Specifically, Applicant submits that Dabiri teaches away from replacing the radio frequency quadrupole (RFQ) linear accelerator in a transportable radioisotope product facility of Dabiri with the cyclotron of Bergstrom for several reasons.

First, Applicant submits that Dabiri discloses that an amount of shielding for a radio frequency quadrupole (RFQ) linear accelerator is less than an amount of shielding for a cyclotron. In particular, Dabiri discloses that the radio frequency quadrupole (RFQ) linear accelerator is based on a neutron-poor reaction which results from a  $^3\text{He}^{++}$  bombardment of the target material and thus, significantly reduces the amount of shielding that is required around the target chamber.” See, column 3, lines 27-30. Specifically, Dabiri discloses that “due to the neutron-poor nature of the  $^3\text{He}^{++}$  beam and resulting reactions, no shielding around the accelerator and little shielding around the target chamber is required relative to existing cyclotron-based PET systems.” See, column 4, lines 49-53 (emphasis added). As illustrated in Figures 2 and 10 of Dabiri, “no shielding is required around the radio frequency quadrupole (RFQ) 34, thereby significantly reducing the quantity of shielding required.” See, e.g., column 6, lines 55-57. Particularly, Dabiri discloses that “unlike most reactions for proton and deuteron-based systems which involve neutrons in the final state, most of the  $^3\text{He}$ -based reactions involve a charged particle in the final state. Such particles can be easily shielded by sheets of aluminum or the target casting itself. See, e.g., column 7, lines 21-26. Therefore, Dabiri discloses that the reduced shielding requirements, coupled with the small radio frequency quadrupole (RFQ) linear

accelerator, makes possible a PET system to efficiently generate the needed radionuclides for PET applications. *See, e.g.*, column 3, lines 36-41. Thus, Applicant respectfully submits that the radio frequency quadrupole (RFQ) linear accelerator of Dabiri requires less shielding than the cyclotron of Bergstrom and therefore one having ordinary skill in the art would not have replaced the radio frequency quadrupole (RFQ) linear accelerator with a cyclotron.

Second, Applicant respectfully submits that Dabiri discloses that an amount of power consumed for a radio frequency quadrupole (RFQ) linear accelerator is less than an amount of power consumed for a cyclotron. In particular, Dabiri discloses that “advantageously, the radio frequency quadrupole (RFQ) linear accelerator is a small, light-weight device and requires significantly less operating power than does the cyclotron.” *See*, column 3, lines 16-18 (emphasis added). Specifically, Dabiri discloses that the radio frequency quadrupole (RFQ) linear accelerator system “operates on roughly 1/5 of the operating power required by the cyclotron-based PET system.” *See*, column 4, lines 18-20. Dabiri also discloses that “the reduced shielding requirements, coupled with the small RFQ accelerator and the relatively low power requirements therefore, as well as the efficient use of the target material, makes possible a PET system” to efficiently generate the needed radionuclides for PET applications. *See, e.g.*, column 3, lines 36-41. Therefore, Applicant respectfully submits that one having ordinary skill in the art would not replace the low power consumption radio frequency quadrupole (RFQ) linear accelerator of Dabiri with the high power consumption cyclotron of Bergstrom.

Third, Applicant respectfully submits that Dabiri discloses that an amount of neutrons produced by a radio frequency quadrupole (RFQ) linear accelerator is less than an amount of neutrons produced by a cyclotron. In particular, Dabiri discloses that the  $^3\text{He}$ -based reactions

“significantly reduce the neutron production in the targets relative to that in the protons and deuteron targets.” *See, e.g.,* column 7, lines 27-29. Moreover, Dabiri discloses that the “low neutron production significantly reduces the shielding requirements” of the radio frequency quadrupole (RFQ) linear accelerator system. *See, e.g.,* column 7, lines 36-38. Therefore, Applicant respectfully submits that one having ordinary skill in the art would not replace the low level neutron producing radio frequency quadrupole (RFQ) linear accelerator of Dabiri with the high level neutron producing cyclotron of Bergstrom.

Fourth, Applicant respectfully submits that Dabiri discloses that the enriched target material for a radio frequency quadrupole (RFQ) linear accelerator is more readily available compared to the enriched target material for cyclotron. Specifically, Dabiri discloses a positron emission tomography (PET) system that does not require a cyclotron to generate a proton/deuteron beam. The PET system of Dabiri uses a radio frequency quadrupole (RFQ) linear accelerator to accelerate a readily available ion source to produce a  $^3\text{He}^{++}$  beam to around 8 MeV. *See, e.g.,* column 3, lines 7-12. Also, Dabiri discloses that a cyclotron system requires enriched target materials if the desired radionuclides are to be efficiently produced by the proton/deuteron beam and such enriched target materials are not readily available, and costly to produce. *See, e.g.,* column 2, lines 35-39. Thus, Applicant respectfully submits that the enriched target material for a radio frequency quadrupole (RFQ) linear accelerator of Dabiri is more readily available than the cyclotron of Bergstrom and therefore one having ordinary skill in the art would not have replaced the radio frequency quadrupole (RFQ) linear accelerator with a cyclotron.

Furthermore, Applicant respectfully submits that Dabiri discloses that extraction is not required for a radio frequency quadrupole (RFQ) linear accelerator as is required for a cyclotron. Particularly, Dabiri discloses that “no extraction system is required to extract the  $^3\text{He}^{++}$  beam from the radio frequency quadrupole (RFQ) linear accelerator as is required to extract a proton/deuteron beam from a cyclotron.” *See, e.g.*, column 4, lines 40-43. Also, Dabiri discloses that beam activation problems associated with a cyclotron are eliminated with the radio frequency quadrupole (RFQ) linear accelerator system. Specifically, Dabiri discloses that the radio frequency quadrupole (RFQ)-based accelerator system has no beam activation problems as are common with proton/deuteron beam systems. *See, e.g.*, column 6, lines 50-52. In addition, Dabiri discloses that the  $^3\text{He}^{++}$  target reactions have the property that fewer neutrons are produced per isotope nucleus than with low energy proton or deuteron based systems which results in the elimination of the radiation shielding for the accelerator. *See, e.g.*, column 16, line 67 to column 18, line 3.

For all of the foregoing reasons, Applicant respectfully submits that Dabiri teaches away from replacing the radio frequency quadrupole (RFQ) linear accelerator with the cyclotron of Bergstrom, as alleged by the Office Action. Therefore, Applicant respectfully submits that the Office Action failed to establish a prima facie case of obviousness to combine Dabiri and Bergstrom as alleged by the Office Action because the claim rejection is improperly based on hindsight, as Dabiri in fact strongly teaches away from the use of a cyclotron for many reasons described above. Accordingly, reconsideration and withdrawal of the rejection of claim 1 is respectfully requested.

Regarding dependent claims 2-12 and 29, it is respectfully submitted that the obviousness rejection of claims 2-12 and 29 has become moot in view of the deficiencies of the primary references (i.e., Dabiri and Bergstrom) as discussed above with respect to independent claim 1. That is, claims 2-12 and 29 are dependent upon independent claim 1 and thus incorporate all of the limitations of independent claim 1. Also, the secondary references (i.e., AAPA, Wiberg, Strawson, Ashley, Zhu, and Armel) fail to disclose, or even suggest, the deficiencies of the primary references as discussed above with respect to independent claim 1. Indeed, the Examiner does not even assert such. Thus, the combination of the secondary references with the primary references also fails to disclose, or even suggest, the deficiencies of the primary references as discussed above with respect to independent claim 1. Accordingly, claims 2-12 and 29 are allowable over the combination of the secondary references with the primary references at least by virtue of their dependency on independent claim 1. Moreover, claims 2-12 and 29 recite additional features which are not disclosed, or even suggested, by the cited references taken either alone or in combination.

In view of the foregoing, it is respectfully requested that the aforementioned obviousness rejection of claims 1-12 and 29 be withdrawn.

Regarding claim 30, this claim recites subject matter related to claim 1. Thus, the arguments set forth above with respect to claim 1 are equally applicable to claim 30. Accordingly, it is respectfully submitted that claim 30 is allowable over Dabiri and Bergstrom for the same reasons as set forth above with respect to claim 1.

Moreover, the Office Action asserts, and Applicant agrees, that Dabiri and Bergstrom fail to disclose, or even suggest, "a synthesis unit and a packaging area, wherein the packaging area

allows labeling of containers containing the radiopharmaceutical and entering of records of production and delivery of the pharmaceutical,” and “enclosing the cyclotron inside the manufacturing facility, wherein the manufacturing facility is designed to satisfy substantially all legal and regulatory requirements of the jurisdiction in which the site is located,” as presently claimed. The Office Action asserts that a “person of ordinary skill in the art would recognize the necessity for a specialty packaging area as taught by Zhu, and realize that if a facility is entirely transportable and self-contained as disclosed by Dabiri and Armel, respectfully, the manufacturing facility would have to be equipped with the packing equipment and associated packaging room prior to transporting the facility to its designated site.” *See*, page 11 of the Office Action. Applicant respectfully disagrees. Applicant respectfully submits that Armel discloses that irradiators for subjecting food stuffs and other materials to radiation, which are small enough and light enough to be transported from place to place. *See*, e.g., column 1, lines 11-15. In contrast, Zhu discloses radiation-resistant shields that allow improved handling of radioactive materials used in the healthcare industry. *See*, e.g., column 1, lines 7-9. Specifically, Zhu discloses that in the field of nuclear medicine, radioactive materials known as radiopharmaceuticals are used in positron emission tomography (PET) and when transporting radiopharmaceuticals massive lead shields are used as transport containers. *See*, e.g., column 1, lines 53-62. Therefore, one having ordinary skill in the art would not have combined the massive lead shields for radiopharmaceuticals of Zhu and the irradiators of Armel for subjecting food stuff to radiation.

The Office Action alleges that it is conventional practice to design a facility to satisfy substantially all legal and regulatory requirements of the jurisdiction in which the site is located

and it appears that the Examiner is taking Official Notice without documentary evidence to support this conclusion. Applicant traverses this rejection because there is no support in the record for the conclusion that the identified features are “old and well known.” In accordance with MPEP § 2144.03, the Examiner must cite a reference in support of his position and Official Notice unsupported by documentary evidence should only be taken by the Examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. (emphasis added). Specifically, Applicant respectfully submits that because a manufacturing facility is mobile and therefore may not be subjected to control of any jurisdiction, it would not be conventional practice to design a facility to satisfy substantially all legal and regulatory requirements of the jurisdiction in which the site is located.

The Office Action alleges that it is conventional to place a synthesis unit in a laboratory and it appears that the Examiner is taking Official Notice without documentary evidence to support this conclusion. Applicant traverses this rejection because there is no support in the record for the conclusion that the identified features are “old and well known.” In accordance with MPEP § 2144.03, the Examiner must cite a reference in support of his position and Official Notice unsupported by documentary evidence should only be taken by the Examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. (emphasis added). Specifically, Applicant respectfully submits that various laboratories may contain different units, for example, a semiconductor testing laboratory may contain various testing components and may not contain a synthesis unit, especially a biomedical synthesis unit.

The Office Action alleges that it is conventional practice to equip a radioactive material production facility with a clean room for dispensing the radioactive material into containers and it appears that the Examiner is taking Official Notice without documentary evidence to support this conclusion. Applicant traverses this rejection because there is no support in the record for the conclusion that the identified features are "old and well known." In accordance with MPEP § 2144.03, the Examiner must cite a reference in support of his position and Official Notice unsupported by documentary evidence should only be taken by the Examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. (emphasis added). Specifically, Applicant respectfully submits that because a cyclotron requires massive lead shields, there may not be space for a clean room. Therefore, Applicant respectfully submits that it is not conventional practice to equip a radioactive material production facility with a clean room for dispensing the radioactive material into containers.

Accordingly, reconsideration and withdrawal of the rejection of claim 30 is respectfully requested. The dependent claims are allowable for at least the same reasons that claim 30 is allowable.

Regarding claims 31-34, these claims are dependent upon independent claim 30. Thus, since independent claim 30 is allowable as discussed above, claims 31-34 should also be allowable at least by virtue of their dependency on independent claim 30. Moreover, these claims recite additional features which are not disclosed, or even suggested, by the cited references taken either alone or in combination.

In view of the foregoing, it is respectfully requested that the aforementioned obviousness rejection of claims 30-34 be withdrawn.

### 3. Conclusion

In view of the above remarks, Applicant respectfully submits that the present application is in condition for allowance, and notice to that effect is respectfully solicited. If there are any questions regarding this Amendment or the application in general, the Examiner is encouraged to contact the undersigned to expedite prosecution.

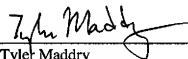
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Respectfully submitted,

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